

REMARKS

Prior to the present reply, claims 67, 69-108 were pending. Due to a Restriction Requirement claims 70, 86-88, 97, 98, and 103-106 are withdrawn from consideration. Claims 67, 69, 71-85, 89-96, 99-102, 107, and 108 are thus examined. These claims are objected to. These claims are also rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 89-91 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The application is also objected to for not complying with the sequence listing requirements. Each of these rejections and objections are addressed below.

Claim amendments

In the present reply, claim 67, 69, 73-75, 77, 79, and 92 have been amended, claims 70, 83-91, and 101-108 have been canceled, and new claims 109-118 have been added. Claim 67 has been amended to require that the extendin-4 peptide have an alpha-aspartate (Asp) at position 28. Claim 67 has been further amended to require and 0-3 deletions at positions 36-38. Support for this change is found, for example, at page 5, lines 29-31, of the specification. Claim 75 has been amended to recite peptides that read on amended claim 67. Claims 75 and 77 has been amended to delete peptides that do not read on amended claim 67. The dependencies of claim 79 have been amended in view of the cancelation of claim 70. Claim 92 has been amended to delete language referring to

several diseases. Claims 67, 69, 73-75, and 77 have also been amended to delete the word “stabilized.” Support for new claims 109-112 is found, for example, in claim 75. Support for new claims 113-118 is found, for example, in claim 77. These amendments add no new matter.

Sequence listing requirements

The Office has objected to the application as failing to comply with the sequence listing requirements under 37 C.F.R. §§ 1.821-1.825. Applicants have therefore provided a sequence listing reciting each sequence appearing the specification and claims. The specification and claims have also been amended to include sequence identifiers, as required by 37 C.F.R. §1.821(d). These changes add no new matter. Applicants submit that the application now is in compliance with the sequence listing requirements.

Claim objections

Claims 67, 75, 83, 92, 101, 102, 107, and 108 are objected to for reciting nonelected polypeptides or diseases such as metabolic disorders, gastric emptying or eating disorders. Claims 101, 102, 107, and 108 have been canceled, thus rendering the objection to these claims moot. Claim 67 has been amended to recite that the peptide has an alpha-aspartate (Asp) at position 28 and a deletion of 0-3 of residues at positions 36-38 of the exendin-4 sequence. Claims 75 and 77 have been amended to recite only peptides

that read on amended claim 67. Claim 92 has been amended to recite only diabetes type I, in accordance with the Restriction Requirement. On the basis of these amendments, applicants respectfully request that this objection be withdrawn.

Claims 69, 71-74, 76, 78-82, 84, 85, 89-91, 93-96, 99, and 100 are objected to for depending directly or indirectly from an object to or withdrawn claim. As these claims all depend from claim 67 directly or indirectly, which has been amended as described above, applicants submit that these claims are likewise free from this objection. The objection to these claims may also be withdrawn.

The Office also objects to claims 79, 101, and 102 on the basis of syntax. Claims 101 and 102 have been canceled, thus rendering the objection to these claims moot. With regard to claim 79, applicants submit that the claim is in proper alternative form as written. The language used in the claim, i.e., “any of one of claims 67 and 71-78,” is an acceptable multiple dependent claim wording, as set forth in M.P.E.P. § 608.01(n)(I)(A). This objection may also be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 67, 69, 71-85, 89-96, 99-102, 107, and 108 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Compliance with the enablement requirement can be satisfied by providing at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. M.P.E.P. § 2164.01(b).

In making the rejection, the Office, while acknowledging that the compound [Asp²⁸]Exendin-4 (1-39) is enabled, indicates that the specification is not enabling for compounds having 1-5 amino acids deletions at the residues corresponding to positions 34-38. The Office asserts that the specification does not provide any data showing that the claimed compounds are more stable than a composition comprising Exendin-4.

Without assenting to this rejection, applicants respectfully traverse the rejection as applied to the amended claims. As noted above, claim 67 has been amended to require that the peptide have 0-3 deletions of the amino acids at positions 36-38 of the exendin-4 sequence and to require an alpha-aspartate (Asp) amino acid at position 28. Claim 67 and its dependent claims have also been amended to delete language regarding stabilization.

The specification provides sufficient support for at least one method of making and using the invention bearing a reasonable correlation to the scope of amended claim 67 and its dependent claims. As acknowledged by the Office (page 6 of the action), making a mutation in a protein is well known in the art. Further, the specification provides data supporting those of exendin-4 peptides that read on amended claim 67 in reducing blood glucose levels. As noted by the Office, [Asp²⁸]Exendin-4 (1-39)-NH₂ was observed to reduce blood glucose levels, as shown in Figure 8. In addition, compounds having

deletions of amino acids at positions 36-38 of the exendin-4 sequence also are able to reduce blood glucose levels. In particular, Compound 1 (des Pro³⁶Exendin-4 (1-39)-Lys₆-NH₂) and Compound 5 (des Pro³⁶[Asp²⁸]Exendin-4 (1-39)-NH₂) were both capable of decreasing blood glucose levels, as shown in Figures 5, 6, and 8.

The specification thus provides data showing that compounds optionally having a deletion at positions 36-38 and an Asp at position 28 are capable of reducing blood glucose levels. As these compounds bear a reasonable relation to the scope of claim 67, applicants submit that this disclosure enables claim 67, and its dependent claims. On this basis, applicants respectfully request that the rejection of these claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 89-91 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. These claims have now been canceled, thus rendering this rejection moot. The rejection of claims 89-91 may therefore be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office action for three (3) months, to and including November 5, 2008. Deposit Account No. 03-2095 is being charged for payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,



Jeffrey C Kessler
Reg. No. 57,727

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Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045